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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,592	03/19/2004	William Galbraith	80154	9558
26253	7590	02/04/2005	EXAMINER	
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			YU, MELANIE J	
		ART UNIT	PAPER NUMBER	
		1641		

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/804,592	GALBRAITH, WILLIAM	
	<b>Examiner</b>	<b>Art Unit</b>	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 July 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-49 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6 and 24-31 are drawn to an apparatus, classified in class 422, subclass 50.
  - II. Claims 7-12 are drawn to a method for producing an albumin-depleted sample, classified in class 435, subclass 4.
  - III. Claims 13-17 are drawn to an albumin depleted sample, classified in class 436, subclass 518.
  - IV. Claims 18-23 are drawn to a method of binding a bromosulfophthalein ligand, classified in class 435, subclass 7.1.
  - V. Claims 32-37 are drawn to a method for producing a protein depleted sample comprising a sample with one or more additional proteins, classified in class 435, subclass 174.
  - VI. Claim 38 is drawn to an albumin protein depleted sample with one or more additional proteins, classified in class 436, subclass 530.
  - VII. Claims 39-42 are drawn to a spin column, classified in class 422, subclass 58.
  - VIII. Claims 43-46 are drawn to a method for producing an albumin-depleted sample comprising a spin column, classified in class 435, subclass 288.6.
  - IX. Claims 47-49 are drawn to a kit, classified in class 422, subclass 59.

The inventions are distinct, each from the other because of the following reasons:

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2. Inventions of a) each of groups I, VII, and IX and b) each of groups II, IV, V, and VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatuses of groups I, VII, and IX can be used in any of the materially different processes of groups II, IV, V, and VIII.

3. Inventions of a) each of groups I, VII, and IX and b) each of groups III and VI are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the products of groups III and VI can be made by the apparatus of group I, VII, or IX.

4. Inventions of each of groups I, VII, and IX are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The product of group I requires an insoluble support, which is not required of the products of groups VII and IX. The product of group VII requires an albumin-binding resin comprising one or more ligands capable of binding albumin, which is not required of the products of groups I and IX. The product of group IX requires a receiving tube having a lid, which is not required of the products of group I and VII.

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5. Inventions of each of groups II, IV, V, and VIII are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the methods have different functions. The method of group II requires running a sample over an insoluble support having attached thereto a ligand, which is not required of the methods of groups IV, V, and VIII. The method of group IV requires alkaline conditions to produce a bromosulfophthalein anion, which is not required of the methods of groups II, V, and VIII. The method of group V requires a sample including albumin and one or more additional proteins, which is not required of the methods of groups II, IV, and VIII. The method of group VIII requires providing a spin column, which is not required of the methods of groups II, IV, and V.

6. Inventions of a) each of groups II, IV, V, VIII and b) each of groups III and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products of groups III and IV can be made any the materially different processes of groups II, IV, V, or VIII.

7. Inventions of group III and group VI are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The sample of group III requires albumin depletion, which is not required by the sample of group VI. The sample of

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group VI requires albumin and one or more additional proteins, which is not required by the sample of group III.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. A telephone call was made to Ms. Nanette Thomas on December 21, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie Yu  
Patent Examiner  
Art Unit 1641



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02/02/05